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TWO PRUDENTIAL PLAZA, SUITE 4900

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CHICAGO, IL 60601-6731

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

1. Claims 1-55 and 57-77 are pending in the application.

Election/Restrictions

2. In view of Applicant's argument in traversal, and the lack of any teaching regarding scytovirins in the prior art, the restriction is withdrawn.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on November 10, 2004 in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

4. Claims 64 and 65 objected to because of the following informalities: these claims include the phrase "The method of any of claim 39." It is suggested that the claims be amended to read on - - The method of claim 39...- -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1, 3-46, 47-52, 55, and 57-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected on three grounds. The first basis applies to claims 1, 3-16, 18-46, 47-52, 55, and 57-77. These claims are drawn to a genus of compositions comprising variants and fragments of SEQ ID NO: 1 that retain their antiviral activity, and to a genus of methods for using such compositions for the inhibition of a virus (or to nucleic acids that encode such proteins, or antibodies that bind them). These claims are rejected because there is insufficient descriptive support for any variant or fragment of the protein of SEQ ID NO: 1 (and therefore for the methods of using or other related compounds) that retains the antiviral activity of SEQ ID NO: 1.

The second basis of the rejection applies to claim 17. This claim is rejected because there is insufficient written description support for the subgenus of nucleic acids specifically isolated from *Scytonema varium*.

The third basis applies to 57, which reads on an antibody that binds to an the scytovirin of claim 1, wherein the antibody comprises an internal image of the an envelope protein of an immunodeficiency virus.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

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The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

Further, even in cases where multiple species within a claimed genus have been disclosed, such does not necessarily demonstrate possession of the genus. See, *In re Smyth*, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing *Smyth* for support). Where there is uncertainty in the operability of undisclosed embodiments, an application may be found not to have provided adequate descriptive support for a claimed genus.

As indicated above, the claims 1, 3-16, 18-46, 47-52, 55, and 57-77 are drawn to the antiviral protein of SEQ ID NO: 1, and antiviral variants and fragments thereof (or methods of use of related compositions thereto). However, the application does not disclose any such variants or fragments, and provides no identification as to what fragments of the protein may be

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required for the protein's antiviral activity, and no identification as to what residues, structures, or sequences are required to the activity. Thus, the present application provides neither a number of species that represent the full scope of the genus claimed (i.e. provides no examples of operable fragments or variants), nor identifies any structural or non-functional feature that correlates to the required function.

In view of the lack of either species or non-functional identification sufficient to demonstrate possession of the full genus of scytovirin variants and fragments as claimed, the indicated claims are rejected as lacking adequate written description support. Moreover, because the Applicant lacks adequate descriptive support for the protein variants and fragments, the Applicant also lacks support for nucleic acids encoding, and antibodies binding, such variants and fragments.

The second basis of the rejection is on the grounds that there is insufficient descriptive support for the genus of nucleic acids described in claim 17. This claim is drawn to a nucleic acid encoding the protein of SEQ ID NO: 1, wherein the nucleic acid has been isolated or purified from *Scytonema varium*. It is noted that the application discloses the sequence of SEQ ID NO: 1. In view of the knowledge in the prior art of the genetic code by which such proteins are encoded by nucleic acids, the provision of this sequence provides support for a genus of polynucleotides that encode the protein. However, claim 17 reads on a subgenus of such polynucleotides wherein the nucleic acid sequences are purified or isolated from *Scytonema varium*. There is, however, no description of or examples of any such nucleic acid. The application provides no means by which to distinguish between nucleic acids that may be

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isolated or purified from the indicated source from those functional variants permitted by the redundancy of the genetic code. Moreover, knowledge in the art of a method for the identification of such nucleic acid fails to provide adequate support for the sequences that may be so identified. See e.g., *University of Rochester v. G. D. Searle & Co.*, 69 U.S.P.Q.2d 1886, at 1895 (CAFC 2004- stating that provision of a method for the identification of a compound does not provide support as to which compounds may be so identified). In view of the above, the application lacks adequate support for the claimed genus of nucleic acids.

Finally, the application also lacks adequate descriptive support for the antibodies of claim 57. This claim is drawn to an antibody that binds to scytovirin wherein the antibody comprises an internal image of a gp120 protein of an immunodeficiency virus. The claim is rejected because, while the application indicates that the scytovirin protein is capable of binding to the HIV envelope proteins, the Applicant has not identified what regions of these proteins the proteins react with. Thus, the application does not teach what regions of these proteins should be included in the internal images of the proteins of the antibodies described by this claim. Moreover, it is noted that the claim also indicates that the internal image may be of a gp120 protein of any immunodeficiency virus. However, the application demonstrates only that scytovirin binds gp120 of HIV. There is no demonstration of binding between a scytovirin and any other immunodeficiency virus. Nor is there any indication that the region of HIV gp120 binds is a region shared by other immunodeficiency viruses. In view of the presence of only the single working example, and the lack of any evidence that the protein would be capable of binding to a gp120 protein of any other immunodeficiency virus, or as to what regions of the

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gp120 protein of any immunodeficiency virus the scytovirin would bind, the application has not provided adequate descriptive support for genus of antibodies claimed.

7. Claims 37-51, 64-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting HIV infection of a biological sample, does not reasonably provide enablement for methods of inhibiting HIV virus infection of a host or of inhibiting infection by other viruses than HIV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 37-46 and 64-77 read on methods for inhibiting the viral infection of a host comprising the administration of a composition comprising a scytovirin protein, or nucleic acid encoding such. These claims are rejected on two grounds. First, the claims lack adequate enabling disclosure for the use of the described compositions for the inhibition of HIV infection in a host organism. The second ground of rejection, which also applies to claims 47-51 (drawn to methods of inhibiting a virus in a biological sample or on an inanimate object), is that the claims lack adequate enabling support for methods of using the scytovirin compositions for the inhibition of any virus.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working

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examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed most relevant are the breadth of the claims, the presence or absence of working examples, the amount of guidance or direction provided, the state of the prior art, and the unpredictability of the art.

With respect to the first ground of rejection, which applies to claims 37-46 and 64-77, that there are insufficient teachings to enable the inhibition of viral infection of a host organism, it is noted that the application provides no demonstration of *in vivo* inhibitory effect against any virus. All of the examples of the application are limited to the *in vitro* inhibition of HIV infection. Thus, there is no demonstration in the application of the ability of the indicated compositions to act *in vivo* to inhibit HIV (or any other viral) infection as is required by the claims.

The art indicates that the mere identification of compounds that inhibit *in vitro* HIV activity is not sufficient to demonstrate *in vivo* inhibition of viral infection. Rather, the art provides several challenges being faced, and indicates an acceptance in the art that HIV therapy is an unpredictable art. For example, references in the art indicates that, while there are treatments available for HIV infection, such treatments involve the use of multiple drugs targeting multiple phases of the viral life cycle simultaneously. See e.g., Marcus et al., *Intervirology* 45: 260-66, pages 263-64 (teaching that effective therapies require the use of multiple drugs, and that, due to the highly mutagenic nature of the virus, it should be expected that

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drug resistant varieties of virus will be present in every infected person); and Molla et al., Curr Opin Biotech 14:634-40, page 634 (noting that treatment of HIV infection with only one drug at a time, monotherapy, leads to rapid development of drug resistant strains). See e.g., Gait et al., Trends Biotech 13: 430-38. Gait teaches that, while such methods of drug identification have sped up the process of drug discovery, no single drug effective for treatment of the infection has been developed. Page 430 (stating that while drugs that lead to reduction in viral load have been identified, such benefits are short-lived), and page 437 (teaching that drug resistance is a real problem in the efficacy of drugs, and that resistant strains generally pre-exist in HIV infected individuals). Thus, the art teaches that the design of anti-HIV drugs is an endeavor wrought with challenges. In addition to the native mutagenicity and heterogeneity of the virus itself, those in the art additionally face unpredictable factors such as low serum half-life, poor bioavailability, and drug clearance of the drugs themselves. Page 437. Thus, the art indicates that the art surrounding the inhibition of HIV infection is wrought with complexity and uncertainty, and that the identification of a potential anti-HIV agent in vitro is insufficient to demonstrate that the compound would be effective in inhibiting HIV infection in vivo (i.e. in a host).

In view of the complexity and uncertainty in the art, and the lack of any demonstration of in vivo efficacy of the claimed compositions, the application has not enabled the practice of the claimed invention to the extent of inhibiting an HIV infection in a host.

The second basis of the rejection, which applies to all of the rejected claims, is concerned with the breadth of the claims, which read on the use of the claimed compositions to inhibit *any* viral infection. As was indicated above, the sole example provided in the application is a

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demonstration of in vitro anti-HIV activity. The application provides no demonstration that the compositions are effective against any other virus, or any guidance or direction as to what other viruses the compositions may be capable of inhibiting. While the application teaches that the compound is able to bind to the envelope proteins of the virus, there is no indication that this ability would correlate to the protein's ability to bind to viral proteins or inhibit viral infections generally. In view of the lack of examples of viruses other than HIV, and the lack of any guidance or direction as to what other viruses the compounds may be capable of inhibiting, the claims are rejected as exceeding the scope of enablement because the application is not enabling for the practice of the claimed methods against viruses in general. Rather, the teachings of the application have provided enabling support only for anti-HIV activity (in vitro).

8. Claims 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on methods of inhibiting viral infection of a mammal comprising the administration of an antibody that binds to the scytovirin of claim 1. These claims are rejected because the application teaches that the scytovirin of claim 1 is itself an inhibitor of viral (HIV) infection. If this is the case, then an antibody that binds this protein, if capable of any inhibiting activity at all, would inhibit the activity of this protein, thereby inhibiting the protein's ability to inhibit HIV infection. I.e., the antibody would interfere with the anti-HIV activity of the scytovirin. These claims are therefore rejected as lacking enablement.

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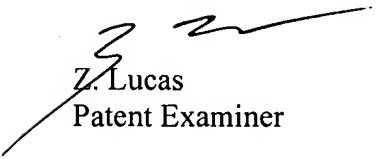
Conclusion

9. No claims are allowed. Claims 2, 53, and 54 are objected to as depending from a rejected claim.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Z. Lucas
Patent Examiner